



PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P-441WO	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/JP2004/000444	International filing date (<i>day/month/year</i>) 20 January 2004 (20.01.2004)	Priority date (<i>day/month/year</i>) 21 January 2003 (21.01.2003)
International Patent Classification (IPC) or national classification and IPC A61K 9/20, 47/10, 47/26, 47/32, 47/36, 47/38		
Applicant NIPPON SHINYAKU CO., LTD.		

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>3</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (<i>sent to the applicant and to the International Bureau</i>) a total of _____ sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (<i>sent to the International Bureau only</i>) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> <p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>

Date of submission of the demand 15 July 2004 (15.07.2004)	Date of completion of this report 06 December 2004 (06.12.2004)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2004/000444

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- This report is based on translations from the original language into the following language _____, which is language of a translation furnished for the purpose of:
- international search (under Rules 12.3 and 23.1(b))
 - publication of the international application (under Rule 12.4)
 - international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

- The international application as originally filed/furnished

- the description:

pages _____, as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

- the claims:

pages _____, as originally filed/furnished

pages* _____, as amended (together with any statement) under Article 19

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

- the drawings:

pages _____, as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

- a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. The amendments have resulted in the cancellation of:

- the description, pages _____
- the claims, Nos. _____
- the drawings, sheets/figs _____
- the sequence listing (*specify*): _____
- any table(s) related to sequence listing (*specify*): _____

4. This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- the description, pages _____
- the claims, Nos. _____
- the drawings, sheets/figs _____
- the sequence listing (*specify*): _____
- any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2004/000444

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-5	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-5	NO
Industrial applicability (IA)	Claims	1-5	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Document 1: EP 361874 A2 (TAKEDA CHEMICAL INDUSTRIES, LTD.) April 4, 1990

Based on the description in document 1 cited in the international search report, the inventions of claims 1-5 lack an inventive step.

The inventions of claims 1-5 will now be compared with the invention of document 1.

Document 1 describes core granules wherein a liquid dispersion of low-substituted hydroxypropyl cellulose is sprayed onto the core granules (claim 1). In addition, it lists spherical granules, etc., containing sucrose, etc., as core granules, and it states that the core granules in themselves may be a different active ingredient other than the active ingredient contained in the dispersion (page 2, line 52 to page 3, line 1) and that the core granules may be mixed with other components to produce tablets (page 4, lines 1-6). Furthermore, these core granules and tablets containing the same are to be used for oral administration, and therefore the particle diameter of the granules and thickness of the tablet are essentially the same particle diameter and thickness of the inventions of claims 4 and 5.

Therefore, the two differ because the former concern a tablet melting quickly in the oral cavity, but the latter does not include this specification.

However, document 1 states that the invention described therein has excellent disintegration properties (page 1, lines 37-43). Moreover, in the field of pharmaceuticals it is conventional practice to alter the dosage form as needed and select the optimal dosage form for the drug to be administered. As a result, this examination finds that persons skilled in the art can prepare the invention described in document 1 with excellent disintegration properties as a preparation that disintegrates in the oral cavity, and no particular advantage is provided thereby.